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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,225

06/30/2003

David Hung

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CYTYC CORPORATION

250 CAMPUS DRIVE

MARLBOROUGH, MA 01752

EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/608,225	Applicant(s) HUNG ET AL.	
	Examiner HONG SANG	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Hung et al.

1. Applicant's response filed on 2/15/2008 is acknowledged.
2. Claims 1-3, 5, 7, and 13-15 are pending and under examination. Claims 4, 6, 8-12, and 16-70 have been cancelled.

Response to Arguments

Claim Rejections - 35 USC § 103

3. The rejection of claims 1-3, 5, 7, and 13-15 under 35 U.S.C. 103(a) as being unpatentable over Fabian et al. (J. Cell Biochem., 1993, 17G: 153-160, IDS), in view of Sauter et al. (British J. Cancer, 1997, 76(4): 494-501, IDS), JAMA (JAMA, 1973, 224 (6): 823-827), and Knight et al. (Ann. Clin. Res., 1980, 12(15): 202-207) is maintained.

The response states that none of the cited reference teaches a method of ductal lavage. The response states that the obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. The response states that the examiner failed to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied reference, or in the form of generally available knowledge that one having ordinary skill in the art would have been motivated to make the claimed invention and would have had a reasonable success in making the claimed invention.

Applicant's arguments have been carefully considered but are not persuasive. The JAMA reference teaches a method for early detection of breast cancer in a patient

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comprising inserting hair-like catheters into breast ducts with the help of an operating microscope, flushing the ducts with saline for cell studies; and b) examining the fluid to identify abnormal cells (see page 825, left column, 3rd and 4th paragraph, and page 826, right column, 3rd paragraph). Therefore, the JAMA reference teaches a method of ductal lavage. Applicant's arguments that the examiner uses hindsight reasoning to establish the *prima facie* case are not persuasive. "Any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *Ln re McLaughlin* 443. F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). In the instant case, Fabian et al. teach a method for early detection of breast cancer comprising cytologically examining ductal fluid and further detecting breast cancer markers including estrogen receptor expressed on the ductal epithelial cells. The only difference between Fabian et al. and the instant invention lies in the way that the ductal fluid is collected; whereas Fabian et al. used fine needle aspiration to collect ductal fluid, the instant invention uses nipple aspiration and ductal lavage. Collection of ductal fluid by nipple aspiration and ductal lavage was well known in the art before the instant invention was made as shown by Sauter et al. and the JAMA reference. Sauter et al. teach a non-invasive method for early detection of breast cancer comprising collecting nipple aspirate fluid from a patient, cytologically analyzing the fluid (e.g. computerized image analysis of nipple aspirate fluid epithelial cells), and evaluating the promising cancer markers. The JAMA

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reference teaches a method for early detection of breast cancer in a patient comprising inserting hair-like catheters into breast ducts with the help of an operating microscope, flushing the ducts with saline for cell studies; and examining the fluid to identify abnormal. Thus the use of nipple aspiration or ductal lavage taught by Sauter et al. and the JAMA reference as a alternate way to collect ductal fluid was clearly in the purview of those of ordinary skill in the art and was within the knowledge of those in the art at the time the invention was made. Moreover one would have been motivated to do so because nipple aspiration is simple and non-invasive, and the ductal lavage is shown to be effective on obtaining ductal epithelial cells. One of ordinary skill in the art would have a reasonable expectation of success to obtain ductal epithelial cells by nipple aspiration or ductal lavage of breast milk duct because Sauter et al. teach nipple aspiration and JAMA reference teaches a method of obtain ductal cells by lavage of breast milk duct. Because of these reasons, the rejection is deemed proper and therefore maintained.

4. The rejection of claims 1-3, 5, 7, and 13-15 under 35 U.S.C. 103(a) as being unpatentable over Fabian et al. (J. Cell Biochem., 1993, 17G: 153-160, IDS), in view of Love (US Patent No. 6,221,622B1, Date of Patent: 4/24/2001, effective filing date: 4/28/1998), and Knight et al. (Ann. Clin. Res., 1980, 12(15): 202-207) is maintained.

Applicants failed to response to the rejection; as such the rejection is maintained for the reasons of record.

Double Patenting

5. The rejection of claims 1-3, 7 and 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 13, 15 and 19-21 of U.S. Patent No. 6,610,484B1 in view of the teachings of Fabian et al. (J. Cell Biochem., 1993, 17G: 153-160, IDS), and Knight et al. (Ann. Clin. Res., 1980, 12(15): 202-207) is maintained.

Applicants failed to respond to the rejection; as such the rejection is maintained for the reasons of record.

6. The rejection of claims 1, 7, and 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 11, 13 and 22 of U.S. Patent No. 6,642,009B2, in view of the teachings of Fabian et al. (J. Cell Biochem., 1993, 17G: 153-160, IDS), and Knight et al. (Ann. Clin. Res., 1980, 12(15): 202-207) is maintained.

The response states that the commonly-owned US 6,642,009 does not qualified as prior art under 35 U.S.C. 102(e), (f) or (g), and for this reason, the rejection should be withdrawn.

Applicants' arguments have been carefully considered but are not persuasive. The provisions of 35 U.S.C. 103(c) can only be relied upon to disqualify a prior art under 35 U.S.C. 102(e), (f), or (g), thereby overcome a prior art rejection under 35 U.S.C. 103, however, they cannot be relied upon to overcome an obviousness double patenting

rejection. The obviousness double patenting rejection can be overcome by the filing of terminal disclaimers.

MEPE 706.02 (1) (1) [R-6] states "35 U.S.C. 103(c), as amended by the CREATE Act, continues to apply only to subject matter which qualifies as prior art under 35 U.S.C. 102(e), (f), or (g), and which is being relied upon in a rejection under 35 U.S.C. 103. If the rejection is anticipation under 35 U.S.C. 102(e), (f), or (g), 35 U.S.C. 103(c) cannot be relied upon to disqualify the subject matter in order to overcome or prevent the anticipation rejection. Likewise, 35 U.S.C. 103(c) cannot be relied upon to overcome or prevent a double patenting rejection. See 37 CFR 1.78(c) and MPEP § 804".

Conclusion

7. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang
Examiner, Art Unit 1643
3/27/08

/Christopher H Yaen/
Primary Examiner, Art Unit 1643